MAR 2 1 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
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Contact: Yi Liu
Date of Application: 7/11/2012

2.0 Device information

Trade name: Apps-Health01
Common name: Data management software
Classification name: Data management software

3.0 Classification

Production code: DXN, MNW
Regulation number: 21 CFR 870.2770, 21 CFR 870.1130
Classification: II
Panel: 870 Cardiovascular

4.0 Predict device information

Manufacturer: Andon Health Co., Ltd.
Device: KD-931
510(k) number: K102939

5.0 Device description

Apps-Health01 iHealth App is an iOS software for using with health devices, such as Blood Pressure Monitor and Scale. When used with the health devices, iHealth App could transfer data from the device's memory and count, manage, share the data.

6.0 Intended use

The Apps-Health01 is intended for use in home settings as an aid for people to review, analyze, and evaluate test results which are measured from a blood pressure monitor or scale.

7.0 Summary comparing technological characteristics with predicate device

item	Apps-Health01	KD-931 (K102939)
Product type	software	System(include meter and software)
Indications for use	The Apps-Health01 is intended for use in home settings as an aid for people to review, analyze, and evaluate test results which are measured from a blood pressure monitor or scale.	KD-931 Fully Automatic Electronic Blood Pressure Monitor are for use by medical professionals or at home and are non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.
Software platform	iOS	iOS
Hardware requirements	iPhone, iTouch, iPad	iPhone,iTouch,iPad

Function	Blood pressure: Test or manually input blood pressure data. Weight: Test or manually input body composition data. My calorie Trends: View your calories consumed vs. calories burned. Reminders: Set reminders (Medicine/Measure blood pressure /Measure weight/Sport) to stay focused on your goals. My plan: Add and modify your weight goals. My BP trends: View your blood pressure trends. My weight Trends: View your weight data. History: A customizable view of your historical data. My Diary: Log food and activities to stay on track.	Blood pressure: Test blood pressure data. My BP trends: View your blood pressure trends. History: A customizable view of your historical data.
Meter Compatibility	Scales, Blood Pressure Monitor	Blood Pressure Monitor
Connection with peripheral device by	Bluetooth（HS5 with WIFI additionally,KD-931 by apple 30PIN）	Apple 30PIN
Performance test provided	Software validation	Software validation

8.0 Performance summary

Software validation of Apps-Health01 included system test and unit test.
We also performed the Wireless coexistence test, as well as test according to IEC 60601-1 and 60601-1-2, FCC test.

9.0 Comparison to the predict device and the conclusion

Apps-Health01 is similar with the predicted device
FULLY AUTOMATIC ELECTRONIC BLOOD PRESSURE MONITOR MODEL(K102939), However, Apps-Health01 is only a software, it doesn't include meter. And it can used together with Scales, Blood Pressure Monitor instead of Blood Pressure Monitor only.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Andon Health Co., Ltd.
c/o Ms. Yi Liu
No 3, Jinping Road, Ya' an Street
Tianjin China 300190
CN

Re: K122098
Trade/Device Name: Apps-Health01
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, MNW
Dated: January 3, 2013
Received: January 11, 2013

Dear Ms. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K122098

Device Name: Apps-Health01

Indication For Use:

The Apps-Health01 is intended for use in home settings as an aid for people to review, analyze, and evaluate test results which are measured from a blood pressure monitor or scale.

Prescription Use Yes (21 CFR Part 801 Subpart D) And/Or Over the Counter Use Yes (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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